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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,628	03/06/2002	Nathaniel L. Wilganowski	LEX-0314-USA	9673

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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,628	WILGANOWSKI ET AL.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 11-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 11-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3 and 11-17* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 9 February 2004 has been received and entered in full.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

3. The objection to Claim 12 as set forth at pp. 3 ¶5 in the previous Office Action (7 August 2003) is *withdrawn* in view of Applicant's amendments (9 February 2004).

4. The Rejection of claim 2 under 35 U.S.C. §112 ¶2 as set forth at pp. 21 ¶26-27 in the previous Office Action (7 August 2003) is *moot* in view of Applicant's cancellation of said claim (9 February 2004).

5. The Rejection of **1** under 35 U.S.C. §102(b) for the reasons set forth at pp. 21-22 ¶28 of the previous Office Action (7 August 2003) is *moot* in view of the lack of public disclosure of the nucleotide sequence.

Maintained Objections And/Or Rejections

Oath/Declaration

6. The oath or declaration filed 2 July 2002 is defective. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

7. Applicant arguments are not applicable. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 101

8. Claims **1, 3,** and **11-17** are rejected under 35 U.S.C. §101 because the claimed invention is not supported by a specific, substantial, and credible asserted utility or a well-established utility for the reasons set forth at pp. 3-14 ¶6-9 in the previous Office Action (7 August 2003).

9. Applicant traverses said rejection in their response (9 February 2004) on the following grounds: **(a)** the amino acid sequence of SEQ ID NO: 2 shares 100% sequence identity with a sequence entered in GenBank by Prof. Petzinger (Exhibits A, B, C), **(b)** the Specification lists several tissues where the presently claimed sequence is expressed (pp. 4 lines 3-11), **(c)** the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips as specific markers for human chromosome 4, **(d)** the instantly claimed sequences may be used as probes and primers because only expressed sequences can be used to track gene expression, Applicant believes that a requirement for a "unique" utility has been set forth, and the USPTO issues patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, **(e)** the present nucleotide sequence has a specific utility in the identification of protein coding sequences and mapping a unique gene to a particular chromosome, **(f)** undue experimentation is not required to determine the identity, structure, function, and activity of the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1, **(g)** the claimed sequences identify biologically verified exon splice

junctions, as opposed to splice junctions that may be been bioinformatically predicted from genomic sequence alone, **(h)** the skilled artisan would readily understand that the presently claimed sequence has a number of utilities, **(i)** the need for some experimentation does not render the claimed invention unpatentable pursuant to *In re Brana* (34 USPQ2d 1436 (Fed. Cir. 1995), and **(j)** Applicant discusses their opinion of USPTO policy.

10. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

11. On "**(a)**", the instant Specification as filed does not have any *in vitro* data or art-accepted animal model data to establish a credible, specific, and substantial utility for the amino acid sequence of SEQ ID NO: 2 (encoded by the nucleic acid sequence of SEQ ID NO: 1). Neither sequence homology nor Prof. Petzingter's credentials or supposed beliefs can substitute for data and evidence. The identity, structure, function, and activity of the amino acid sequence of SEQ ID NO: 2 (encoded by the nucleic acid sequence of SEQ ID NO: 1) is a question of fact to be proven by data and evidence not asserted by opinion and argument. It is noted that Exhibits A, B, and C suggest that the utility asserted for the amino acid sequence of SEQ ID NO: 2 (encoded by the nucleic acid sequence of SEQ ID NO: 1) is credible, but it does not support the asserted utilities as specific or substantial.

12. On "**(b)**", the information in the first paragraph of Section 5 of the instant Specification in fact establishes the contrary. The Specification is prophetic as it clearly states, "The NHPs described for the first time herein are novel proteins that may be expressed in..." (pp. 4 lines 1-2). No specificity is established as the transcripts are from a wide range of tissue sources, developmental stages, organs, and glands. Nor does the Specification specify the species from

which the samples were taken, the levels at which the transcripts are present, which the sequences are present, or what conditions the transcripts were found. Also no evidence is presented to show that the experiments were actually performed. Thus no evidence is presented establish a specific utility only prophetic consideration of where the novel sequences may be found.

13. On "**(c)**", the instant Specification in fact establishes the contrary. It is prophetic as it clearly states, "SEQ ID NOs 1-3 are apparently encoded on human chromosome 4..." (pp. 18 lines 21-22). No evidence is presented to show that the experiments were actually performed. The Specification suggests that the nucleotide sequences of SEQ ID NO: 1 may be encoded on chromosome 4 but do not confirm it. Therefore additional experimentation would be required to support his assertion and thus the asserted utility is not substantial. In addition, since no experiments have been shown and no data included in the Specification or the prosecution, it cannot be assumed that the nucleotide sequence of SEQ ID NO: 1 is actually on human chromosome 4 therefore the asserted utility is not specific. Applicant asserts in the absence of evidence and data that the nucleotide sequence of SEQ ID NO: 1 which encodes the amino acid sequence of SEQ ID NO: 2 may be used as specific markers as targets for the discovery of drugs that are associated with human disease(s). However, since no disease, condition, illness, injury, disorder, sickness, ailment, syndrome, deficiency or affliction has been associated with the nucleotide sequence of SEQ ID NO: 1 which encodes the amino acid sequence of SEQ ID NO: 2. Thus it necessitates significant and burdensome experimentation and research to discover if any maladies are associated with said nucleic acid and amino acid sequences. In regards to the patents issued on "DNAchips", they are not under present examination. On the subject of the

wide public use of DNAchips, this is not relevant to the instant prosecution. The Applicant includes a discussion of the financial success of using DNAchips but such companies as Affymetrix, GeneLogic, ABI-Perkin-Elmer, HySeq, Rosetta Inpharmatics and Incyte. The Examiner respectfully notes that none of the aforementioned entities, their inventions, their opinions, or their financial transactions are under instant examination. The issue at hand is whether or not the nucleotide sequence of SEQ ID NO: 1 which encodes the amino acid sequence of SEQ ID NO: 2 has a credible, specific, and substantial utility. To date no evidence or data is present to establish a credible, specific, and substantial utility for the nucleic and amino acid sequences claimed.

14. On "**(d)**", as noted above it has not been established that the nucleotide sequence of SEQ ID NO: 1 has been expressed at all. The Specification suggests that it is in the absence of evidence. Therefore additional research and experimentation is required to establish whether or not the nucleotide sequence of SEQ ID NO: 1 is in fact expressed. Thus the claimed utility is not substantial. Also since it is not known where or if it is expressed the asserted utility is not specific. The Examiner notes that no requirement for a unique utility was set forth in the previous Office Action (7 August 2003). Next on the subject of patents on "treatments for a variety of human diseases", all such patents have meet the requirements of 35 U.S.C. §101 and §112, such is not the case with the instant application. The standard of patentability has not and will not be lowered (see MPEP §2105). Also, Applicant's analogies to batteries, automobile tires, golf balls, and golf clubs are not applicable. The products discussed by Applicant have an inherent and obvious utility; this is not the case with newly identified biological molecules. Genes and proteins of unknown identity, structure, function, and activity have no inherent utility

as it is not readily obvious or apparent as to their structure and function from their sequence alone. Applicant has to establish a utility for said biological molecules; this is not the case with the instant claims. No experiments have been performed nor has any data been included in the Specification. In the instant Specification, Applicant has asserted the identity and function of the included unknown biological materials in the complete and utter absence of any evidence. Predictions and argument do not constitute a real world utility as is required to satisfy the requirements of 35 U.S.C. §101 and 35 U.S.C. §112 ¶1.

15. On "**(e)**", Applicant claims that the instantly claimed nucleotide sequence is dispersed on 6 exons of human chromosome 4 (Exhibit D). This does not meet the requirements for a credible, specific, and substantial utility. The region identified by Applicant has no known function and is listed in Exhibit D as being anything from IFN-γ, a *Listeria monocytogenes* virulence factor, IL-12, a 25-Kda cypotococcal deacetylase, or a tumor-derived cytokine (Exhibit D). It is readily apparent that Applicant has found a stretch of DNA in the database that could be almost any gene except a sodium/bile-like transporter. It is also unclear whether the nucleotide sequence of SEQ ID NO: 1 is a coding region as it is "dispersed on 6 exons" over an entire chromosome. In addition, Applicant has admitted on the record that "Numerous GenBank reports contain references that are merely general in nature, and do not specifically contain the annotated sequence." (Response filed 9 February 2004, pp. 22). Therefore Exhibit D only supports the Examiner's position that the nucleotide SEQ ID NO: 1 (which encodes the amino acid sequence of SEQ ID NO: 2) does not encode any known or identified protein. Therefore substantial experimentation would be required to elucidate its identity. Thus the asserted utility is neither specific nor substantial.

16. On "**(f)**", while the identity, structure, function, and activity of the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1 may constitute a fecund ground for investigation, the CAFC ruled in *Genentech Inc. v. Novo Nordisk A/S* (CA FC) **42 USPQ2d 1001** (1997) that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Citing *Brenner v. Manson,* **383 U.S. 519, 536, 148 USPQ 689, 696** (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Therefore the CFAC stated that tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in the instant specification with respect to the identity, structure, function, and activity of the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1. Further as discussed above, the analysis run in Exhibit D yielded no useful information.

17. On "**(g)**", the claimed sequences are not supported by a credible, specific, and substantial utility. No experimentation, development, or research has been represented as to establish the identity, structure, function, and activity of the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1.

18. On "**(h)**", Applicant's assertions are in error. MPEP 2107.02(IV) clearly states that the Office must make a *prima facie* showing that the clamed invention lacks utility and (B) provide a sufficient evidentiary basis for natural assumption relied upon in establishing the *prima facie*

showing. No evidence is required of the Examiner *per se* as presentably nothing is known about the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1 and since the USPTO does not perform research and development, the burden of experimentation is upon the Applicant. In summary, the references are used to support the Examiner's discussion of the underlying flaw of basing the structure and function of a novel sequence purely on sequence alignments and homology. Applicant's disagreement is noted. Nevertheless no evidence was presented to support a credible, specific, and substantial utility for the nucleotide sequence of SEQ ID NO: 1 or the amino acid sequence of SEQ ID NO: 2. Furthermore the MPEP §2145 clearly states that attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection (MPEP § 2129 and §2144.03). Furthermore, the arguments of counsel cannot take the place of evidence in the record. In the instant case the Applicant is asserting that the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1 is a sodium/bile-like transporter while no data, information, or teaching supports this assertion in the instant Specification {see *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.") and MPEP § 716.01(c)}. Therefore the statements made by the Applicant are assertions in the absence of evidence.

19. On "**(i)**", the fact pattern of *In re Brana* (34 USPQ2d 1436 (Fed. Cir. 1995) has nothing in common with the instant application. In *In re Brana*, the Examiner did not accept the use of cell models to establish utility as an anti-tumor agent and murine data as a reasonable

approximation of a human disease. In the instant case, Applicant has assert in the complete absence of any data or evidence that the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1 is a sodium/bile-like transporter. Therefore *In re Brana* is not relevant.

20. On "**(j)**", the instant application is not in compliance with 35 U.S.C. 101 for the reasons as set forth in the previous Office Action (7 August 2003) and maintained herein. The Examiner *declines* to comment (see MPEP §1701) and respectfully directs all questions and concerns on this matter to the Office of the Commissioner pursuant to 35 U.S.C. §3.

21. The rejection of claims 1, 3, and 11-17 under 35 U.S.C. §101 is maintained.

Claim Rejections - 35 USC § 112

22. Claims **1, 3,** and **11-17** are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for the reasons set forth at pp. 14 ¶10 of the previous Office Action (7 August 2003).

23. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons. The rejection under 35 U.S.C. §101 was maintained. Therefore, Applicant's arguments were not found persuasive and thus are not persuasive for the rejection under 35 U.S.C. §112 ¶1.

24. The rejection of claims 1, 3, and 11-17 under 35 U.S.C. §112 ¶1 is maintained.

25. Claim **1, 12, 13,** and **15** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth at pp. 15-19 ¶11-19 of the previous Office Action (7 August 2003).

26. Applicant traverses said rejection in their response (9 February 2004) on the following grounds: **(a)** Applicant submits that the Examiner has failed to present reasoning sufficient to establish a *prima facie* case supporting the enablement rejection, **(b)** composition claims are enabled by defining any practical use of the claimed invention, **(c)** the need for some experimentation does not render the claimed invention unpatentable pursuant to *In re Brana* (34 USPQ2d 1436 (Fed. Cir. 1995) and *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), **(d)** 100% identity between sequences is not required to establish a functional relationship and Applicant comments on references used in the previous Office Action, **(e)** numerous uses of the claimed sequences do not require knowledge of any functional aspects of the amino acid sequences (or nucleic acid sequences) claimed, and **(f)** there is sufficient knowledge and technical skill in the art for a skilled artisan to be able to make and use the claimed DNA species in a number of different aspects of the invention entirely without further details in the patent specification and the specification need describe the invention only in such detail to enable a person skilled in the most relevant art to make and use it.

27. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

28. On "**(a)**", as discussed above the nucleotide sequence of SEQ ID NO: 1 which encodes the amino acid sequence of SEQ ID NO: 2 is not supported by a credible, specific, and substantial utility. Also, the Applicant claims "an isolated nucleic acid molecule comprising at least 59 nucleotides from SEQ ID NO: 1" while not including any evidence, data, or guidance beyond suggestion to teach the skilled artisan how to make or use the claimed invention.

29. On "**(b)**", again as discussed above the nucleotide sequence of SEQ ID NO: 1 which encodes the amino acid sequence of SEQ ID NO: 2 is not supported by a credible, specific, and substantial utility. Also, the Applicant claims "an isolated nucleic acid molecule comprising at least 59 nucleotides from SEQ ID NO: 1" while not including any evidence, data, or guidance beyond suggestion to teach the skilled artisan how to make or use the claimed invention.

30. On "**(c)**", the fact pattern of *In re Brana* (34 USPQ2d 1436 (Fed. Cir. 1995) has nothing in common with the instant application. In *In re Brana*, the Examiner did not accept the use of cell models to establish utility as an anti-tumor agent and murine data as a reasonable approximation of a human disease. Secondly the fact pattern of *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) is not analogous to the instant application. The question of *In re Wands* was one of experimentation with a known product. In the instant case, Applicant has assert in the complete absence of any data or evidence that the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1 is a sodium/bile-like transporter. Therefore neither *In re Brana* nor Applicant's interpretation of *In re Wands* is relevant.

31. On "**(d)**", Example 10 of the Revised Interim Utility Guidelines Training Materials (Exhibit A) is not relevant to the instant fact pattern. As discussed herein, the nucleotide sequence of SEQ ID NO: 1 and the amino acid sequence of SEQ ID NO: 2 do not share any

significant homology with any known sodium/bile-like transporter. Applicant does not specify any specific shortcomings or errors in the references cited in the previous Office Action (7 August 2003) and as such Applicant's comments are taken as opinion.

32. On "**(e)**" and "**(f)**", while the identity, structure, function, and activity of the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1 may constitute a fecund ground for investigation, the CAFC ruled in *Genentech Inc. v. Novo Nordisk A/S* (CA FC) **42 USPQ2d 1001** (1997) that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. Citing *Brenner v. Manson,* **383 U.S. 519, 536, 148 USPQ 689, 696** (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."). Therefore the CFAC stated that tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in the instant specification with respect to the identity, structure, function, and activity of the amino acid sequence (SEQ ID NO: 2) encoded by the nucleotide sequence of SEQ ID NO: 1. Therefore the claims as instantly presented are an invitation to experiment.

33. The rejection of claims 1, 12, 13, and 15 under 35 U.S.C. §112 ¶1 is maintained.

34. Claim **1, 12, 13,** and **15** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth at pp. 19-21 ¶20-25 of the previous Office Action (7 August 2003).

35. Applicant traverses said rejection in their response (9 February 2004) on the following grounds: **(a)** Applicant only needs to convey the invention with reasonable clarity to the skilled artisan, **(b)** the Examiner has misquoted the USPTO Guidelines (66 Fed. Reg. at 1106), **(c)** disclosure of the nucleic acid sequence of SEQ ID NO: 1 and amino acid sequence of SEQ ID NO: 2 is sufficient to satisfy the written description requirement of 35 U.S.C. §112 ¶1, and **(d)** the skilled artisan would readily be able to distinguish the claimed nucleic acids from other materials on the basis of the specific structural description provided.

36. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

37. On "**(a)**", Claim 1 is drawn to polypeptides having at least 59 contiguous nucleotides with of SEQ ID NO: 1. The claims do not require that the polypeptide possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Thus, the claims are drawn to a genus of polypeptides that is defined by sequence identity (such as a stretch of contiguous nucleotides). No examples, evidence, data, or guidance has been presented.

38. On "**(b)**", real or perceived typos in the previous Office Action (7 August 2003) do not evidence material possession of the claimed invention. Also MPEP §2163 teaches that any perceived failure by Office personal to follow the discussed Guidelines is neither appealable nor petitionable.

39. On "**(c)**", a biomolecule described only by a sequence, without any known or disclosed correlation between that function and the structure of the sequence is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

40. On "**(d)**", furthermore disclosure of a partial sequence without additional characterization of the sequence is not sufficient to evidence possession of the claimed invention {see *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021}. Finally Applicant has not pointed out where the claims are supported, nor does there appear to be a written description of the claimed invention. Material possession of an invention cannot be established through arguments of counsel.

41. The rejection of claims 1, 12, 13, and 15 under 35 U.S.C. §112 ¶1 is maintained.

Summary

42. No Claims are allowed.

43. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

44. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Elizabeth C. Kemmerer

CJN
May 19, 2004

ELIZABETH KEMMERER
PRIMARY EXAMINER